IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, *et al*., **Plaintiffs,** **vs.** **GLAXOSMITHKLINE LLC,** **Defendant.**	**Civil Action No. 2:13-cv-4663-JS** **FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER (DKT. NO. 117)**

PLAINTIFFS' BRIEF IN OPPOSITION TO
DEFENDANT'S *DAUBERT* MOTION [CORRECTED]

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GSK has made a *Daubert* motion against all five of Plaintiffs' experts. GSK's motion rests on misstatements of Plaintiffs' claims, snippets of testimony taken out of context, and a misapplication of *Daubert*'s standards. GSK's motion should be denied.

INTRODUCTION

Expert testimony is admissible if (1) the expert is qualified; (2) the testimony will be helpful to the trier of fact; and (3) the testimony is reliable and fits the facts of the case. *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993).

GSK does not challenge the qualifications of any of Plaintiffs' experts. All are undisputed experts in their fields. Consequently, it is especially appropriate to allow their testimony to be evaluated at trial. *See, e.g., AAMCO Transmissions, Inc. v. Baker*, 2008 WL 5245768, at *4 (E.D. Pa. Dec. 16, 2008) (expert's "vast professional experience, training, and certifications" supported his reliability). As *Daubert* recognizes, the "traditional and appropriate" methods of evaluating expert opinions include "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." 509 U.S. at 596. Rule 702 "embod[ies] a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact" and thus incorporates a "liberal policy of admissibility." *Kannankeril v. Terminix Int'l*, 128 F.3d 802, 806 (3d Cir. 1997). Plaintiffs' expert testimony meets *Daubert*'s standards and should be assessed by a jury.

ARGUMENT

I. The Jury Should Hear Philip Russ's Detailed Analysis Of Cidra's cGMP Violations, Based On An FDA-Approved Methodology Unchallenged By GSK

Philip Russ is the owner and president of an independent consulting firm that provides cGMP compliance services and advice to pharmaceutical manufacturers and other companies.

He has over two decades of experience and is a recognized expert in his field. (SMF ¶ 235.)[1]

Plaintiffs retained Mr. Russ to analyze the nature and extent of Cidra's cGMP violations during the relevant period, 2000 through 2005. He did so by reviewing [redacted] (SMF ¶ 75.)

Mr. Russ used a [redacted] expressly approved by the FDA. (SMF ¶¶ 40, 75.) According to the [redacted] (SMF ¶¶ 40-41; see *id.* ¶ 78.) Based on his review of thousands of documents, [redacted] Because the cGMP violations were systemic, pervasive, and chronic, he [redacted]. (SMF ¶ 237.)

GSK challenges neither Mr. Russ's expertise nor his FDA-approved methodology. Instead, GSK argues that his analysis does not "fit the question before the Court" and "might confuse" the jury because he does not purport to prove that cGMP violations at the plant physically affected any particular products and caused them to be "unsafe or ineffective." (Br. at

[1] Citations in the form "SMF __" refer to the Statement of Material Facts submitted with Plaintiffs' brief in opposition to GSK's motion for summary judgment.

2, 3.) GSK argues that only proof of such physical effects can satisfy the "material impact" standard articulated by this Court in its Rule 12(b)(6) decision. (Br. at 3-4.)

GSK's argument ignores the express terms of the Court's decision. The Court held that proof that GSK's drugs were unsafe or ineffective was unnecessary to establish Plaintiffs' economic injury. (Dkt. No. 105, at 9-10, citing *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig*., 804 F.3d 633 (3d Cir. 2015).) This is a financial fraud case, not a product defect or personal injury case. The Food, Drug and Cosmetic Act ("FD&C Act") explicitly requires that manufacturers comply with cGMPs to ***"assure"*** that drugs are properly manufactured. 21 U.S.C. § 351(a)(1)(2)(B) (emphasis added). In implementing this requirement, the FDA has stated that cGMP compliance is crucial "to ***assure*** that quality is built into the design and manufacturing process at every step." (SMF ¶ 25, emphasis added.)

When cGMP violations are systemic, pervasive, and chronic, they nullify the drug company's legally required assurances. GSK tries to read these assurances out of the case by suggesting that the Court's "material impact" standard requires proof of a specific impact on the physical properties of particular pills or ointments, rendering them unsafe or ineffective. As the Court recognized, however, the issue is whether cGMP violations had a "material impact" on the economic value of Cidra's drugs, rendering them "worthless." (Dkt. No. 105, at 11-12.) The assurance that a drug is properly manufactured, as required by the FD&C Act, is an essential component of the drug's value. (SMF ¶¶ 31-32, 209-11, 249.e, 250, 258.b, 265.) Mr. Russ addresses the question whether Cidra's violations had an impact on GSK's assurances. His analysis "fits" this question and therefore is relevant. His testimony should be heard by the jury.

GSK's other arguments regarding Mr. Russ consist of unfounded assertions and quibbles. For example, GSK asserts that he failed to analyze the impact of cGMP violations on "specific

drugs," and that he "cannot even name the At-Issue Drugs." (Br. at 4.) These assertions are false. Mr. Russ's analysis repeatedly refers to particular drugs and demonstrates [redacted]. (SMF ¶ 236.) More broadly, [redacted]. As noted above, Mr. Russ's methodology is approved by the FDA and unchallenged by GSK. At this stage of the case, GSK cannot argue that his analysis should not be credited. If GSK wants to argue that Mr. Russ misreads the data, GSK can make that argument to the jury.[2]

In addition, GSK argues that Mr. Russ's deposition testimony is "confusing" because in answer to various questions he used the terms [redacted]" (Br. at 4-5.) GSK is quibbling over terminology. Mr. Russ's conclusions are clear, as summarized in his report:

[redacted]

[2] For example, if GSK wants to argue that Mr. Russ failed to give adequate weight [redacted], GSK can do so at trial, but that is not a basis for excluding his opinions under *Daubert*. [redacted] (SMF ¶¶ 106-08.) Indeed, the government's criminal case involving cGMP violations at Cidra specifically alleged that the plant's "laboratory testing procedures were insufficient to assure" that its products were cGMP-compliant. (SMF ¶ 107.) The government's criminal case and related civil proceedings resulted in a felony guilty plea, a $150 million fine and forfeiture, and a $600 million civil settlement. (SMF ¶ 18.)

[redacted] [SMF ¶ 237, emphasis added.]

Nothing in Mr. Russ's deposition detracts from these conclusions. His reports establish that "material non-compliance" means a fundamental lack of the necessary "assurance." Moreover, contrary to GSK's suggestion (Br. at 5), Mr. Russ never treated "material non-compliance" as "synonymous with 'worthless.'" Mr. Russ expressed no opinions of any kind regarding economic value. (SMF ¶ 238.) That subject is addressed by Plaintiffs' other experts: Drs. Perri, Schondelmeyer, and Conti.

Finally, GSK's assertion that Mr. Russ was [redacted] (Br. at 5) misrepresents his testimony. Mr. Russ properly declined to speak for the FDA, particularly with respect to its motives. He also cited ample record evidence [redacted]. (SMF ¶ 239.)[3]

Mr. Russ's analysis addresses central issues in this case: the nature and extent of the cGMP violations at Cidra. His testimony should be heard by the jury.

[3] GSK also misrepresents the record concerning [redacted]. (Br. at 5.) For example, GSK asserts that [redacted] (SMF ¶ 240.)

II. The Jury Should Hear Dr. David Kessler, Former FDA Commissioner, Explain The Term "Material Impact" From A Regulatory Point Of View

Dr. David Kessler was the FDA Commissioner from 1990 to 1997. He was appointed by President George H.W. Bush and continued to serve under President Bill Clinton. As the agency's leader, Dr. Kessler was responsible for all aspects of the FDA's activities, including its cGMP enforcement programs. He is a preeminent authority on FDA policies and practices. (SMF ¶ 241.) Dr. Kessler's opinions include the following (among others):

- [redacted] (SMF ¶ 242.a.)
- [redacted] e. (SMF ¶ 242.b.)
- [redacted]. (SMF ¶ 242.c.)

GSK accepts as admissible all of these opinions (and all other aspects of Dr. Kessler's testimony) except the first one listed above: Dr. Kessler's explanation of the term "material impact" in the context of cGMP regulations. (Br. at 7.) GSK raises two objections. First, GSK argues that ***any*** expert opinion regarding "material impact" -- the issue raised by the Court in its Rule 12(b)(6) decision -- is improper because "materiality" is a "legal term of art" and therefore can only be defined by the Court. (Br. at 8-9.) In addition, GSK argues that Dr. Kessler's explanation is a "personal view" and should be excluded because the specific phrase "material

impact" "does not appear in the FDA's governing statutes or regulations, and is not used by FDA staff." (Br. at 7.) Both of these objections are groundless.

First, Dr. Kessler does not purport to give a legal definition of the term "material impact." Instead, he explains [redacted]. A key test under *Daubert* is whether the expert's opinion will be helpful to the trier of fact. 509 U.S. at 588-89, 591-92. Dr. Kessler's opinion meets that standard because it will help the jury understand how cGMP regulations operate, what the regulations seek to accomplish, and how violations can be evaluated on the spectrum from insignificant to extreme. Nothing in Dr. Kessler's opinion interferes with the Court's ability to define "materiality" as a legal matter. In deciding whether cGMP violations had a material impact, the jury will need to understand and assess highly technical evidence, including testimony presented by the parties' cGMP compliance experts (Philip Russ for Plaintiffs, Ronald Stellon for GSK). Dr. Kessler's opinion will provide the jury with useful guideposts for that assessment. GSK acknowledges that the rest of Dr. Kessler's testimony properly "explains why cGMP compliance is important" and properly "outlines manufacturers' compliance responsibilities." (Br. at 7.) GSK fails to recognize that Dr. Kessler's "material impact" opinion supports and informs those other opinions, which GSK concedes are admissible.

Providing guideposts and explaining general principles are valid and traditional functions of expert testimony. The Advisory Committee Notes on the 2000 amendments to Rule 702 state:

> [I]t might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply these principles to the specific facts of the case. For example, experts might instruct the factfinder on the principles of thermodynamics, or bloodclotting, or on how financial markets

> respond to corporate reports, without ever knowing about or trying to tie their testimony into the facts of the case. ***The amendment [of Rule 702] does not alter the venerable practice of using expert testimony to educate the factfinder on general principles.*** [Emphasis added.]

See U.S. ACCU-Measurements, LLC v. Ruby Tuesday, Inc., 2013 WL 1792463, at *10 (D.N.J. Apr. 26, 2013) (Rule 702's Advisory Committee Notes "explicitly authorize an expert opinion as to general principles"); *Drake v. Allergan, Inc.*, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014) (admitting Dr. Kessler's opinions regarding "the FDA's regulatory scheme in general, FDA's practices and procedures, Allergan's compliance with FDA regulations, the FDA's relationship with pharmaceutical companies, and the standard of care for the pharmaceutical industry").

Second, GSK argues that Dr. Kessler's opinion is a "personal view" and should be excluded because "others within the FDA, including the current Commissioner," might have a different view. (Br. at 10.) But as noted above, Dr. Kessler's opinion is firmly grounded in the underlying policies and objectives of the FD&C Act and cGMP regulations. Furthermore, GSK's assertion as to what others at the FDA might think is mere conjecture. At best, GSK suggests that experts may disagree. Such disagreements are a daily occurrence in litigation. They are not grounds for excluding expert opinions under *Daubert*. *See, e.g., United States v. Mitchell*, 365 F.3d 215, 245 (3d Cir. 2004) ("Experts with diametrically opposed opinions may nonetheless both have good grounds for their views, and a district court may not make winners and losers through its choice of which side's experts to admit, when all experts are qualified."); *In re Asbestos Prods. Liab. Litig.*, 714 F. Supp. 2d 535, 547 (E.D. Pa. 2010) (which "competing experts' opinions should be credited" is for the jury to decide).

Moreover, GSK's cGMP expert, Ronald Stellon, [redacted]

[redacted]

In sum, Dr. Kessler's explanation of "material impact" is neither a "legal opinion" nor a "personal opinion." It is a valid expert opinion under *Daubert*. His opinion will be helpful to the jury. GSK has failed to identify any basis for excluding it.[4]

III. The Jury Should Hear Dr. Matthew Perri's Analysis Of Drug Companies' Marketing Communications And Insurers' Reliance On Those Communications

Dr. Matthew Perri III is a Professor at the University of Georgia. He teaches graduate and undergraduate courses in healthcare and pharmaceutical marketing and related areas. Dr.

[4] GSK asserts that "Dr. Kessler has often confused the appropriate bounds of admissible expert testimony, and aspects of his expert reports or testimony have been excluded on *Daubert* grounds eight times in the last five years." (Br. at 10.) GSK misrepresents the holdings in the cited decisions. (See Br. at 11 n.1.) ***First,*** Dr. Kessler has never been prohibited from testifying -- in the cited cases or in any others. At most, the courts have merely narrowed the scope of his opinions in minor respects or issued general guidance for the presentation of his opinions at trial. *See Allen v. Takeda Pharm. N.A., Inc*., 2014 WL 120973, at *14-16 (W.D. La. Jan. 10, 2014); *Drake v. Allergan, Inc*., 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014); *Wells v. Allergan Inc.*, 2013 WL 7208221, at *1-2 (W.D. Okla. Feb. 4, 2013); *cf. Western Sugar Coop. v. Archer-Daniels-Midland Co*., No. 11-CV-03473, Dkt. No. 594 (C.D. Cal. Oct. 23, 2015) (plaintiffs asked Dr. Kessler to opine on irrelevant statutory matters). ***Second,*** Dr. Kessler has been allowed to opine on "FDA regulatory requirements and procedures" -- the same matters he addresses here – whenever they were found relevant. *In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL 6523833, at *7 (D. Ariz. Dec. 21, 2017) (admitting Dr. Kessler's "opinions concerning the FDA regulatory process and [the defendant's] compliance with the process"); *Drake*, 2014 WL 5392995, at *6 (admitting Dr. Kessler's opinions regarding "the FDA's regulatory scheme in general" and the "FDA's practices and procedures"); *Wells*, 2013 WL 7208221, at *1. ***Third,*** courts have repeatedly affirmed Dr. Kessler's expertise. *E.g*., *Allen*, 2014 WL 120973, at *16 ("Dr. Kessler's experience as former Commissioner of the FDA and his current experience . . . provide ample foundation for his opinion"); *In re Bard,* 2017 WL 6523833, at *7; *Drake*, 2014 WL 5392995, at *6.

Perri received his Ph.D. in pharmacy and marketing in 1985. He has been a consultant to both public and private healthcare insurers and providers, including Georgia's Medicaid program, and has served as chairman of the advisory board that recommends drugs for inclusion on the formulary, or preferred drug list, maintained by the State of Georgia for all State-funded health plans. He has worked as a pharmacist and has served as a consultant and adviser to companies in the pharmaceutical industry. (SMF ¶ 248.)

Plaintiffs retained Dr. Perri to explain [redacted]. His opinions include (among others):

[redacted]

GSK argues that these and all other opinions expressed by Dr. Perri should be excluded because he "employed no definable or reliable methodology." (Br. at 11-12.) GSK also argues that the last opinion listed above -- [redacted] -- is unsupported by any "analysis,

reasoning, or elaboration," and was "specifically disavowed" by Dr. Perri in his deposition. (Br. at 12.) GSK bases these objections on an irrelevant case involving hospice care (*Aseracare*) and patent misrepresentations of Dr. Perri's testimony.

First, contrary to GSK's argument, Dr. Perri's methodology is both definable and reliable. GSK purports not to understand the phrase [redacted] but Dr. Perri explained these principles at length. For example, Dr. Perri stated that [redacted]. (SMF ¶ 250.) Dr. Perri explained further that his opinions [redacted] (SMF ¶ 251.) In addition, Dr. Perri cited [redacted]. (SMF ¶ 252.) Dr. Perri properly relied on this experience as a basis for his opinions.[5]

GSK ignores all of this testimony and relies instead on an irrelevant case, *Aseracare*, in which Dr. Perri's opinions were supposedly excluded "for reasons nearly identical to those that exist here." (Br. at 12.) In *Aseracare*, the government retained Dr. Perri to provide expert testimony regarding Medicare fraud in the hospice industry. The court acknowledged that "Dr.

[5] *See* Fed. R. Evid. 702, Advisory Committee Notes ("Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony."); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience"); *Schneider v. Fried*, 320 F.3d 396, 406 (3d Cir. 2003) (trial court abused its discretion by excluding expert testimony based on relevant experience).

Perri is highly qualified in the fields of pharmacy and general healthcare marketing," but found that the government had failed to present particularized evidence of his experience in the hospice industry. *United States v. Aseracare Inc.*, 2014 U.S. Dist. LEXIS 167970, at *28-29 (N.D. Ala. Dec. 4, 2014). That ruling has no application here, where Dr. Perri's expertise is unchallenged.

GSK also argues that Dr. Perri [redacted] The only "hand-curated" testimony here consists of GSK's collection of snippets and misleading paraphrases. In particular, GSK's accusation that Dr. Perri was told "which testimony should be ignored" is false and irresponsible. Dr. Perri received [redacted][6]

Second, Dr. Perri properly opined that [redacted]. According to GSK, [redacted] (Br. at 14.) GSK thus ignores Dr. Perri's repeated references to evidence -- not just "allegations" -- in support of his opinions. (SMF ¶ 254.)

[6] Given Dr. Perri's extensive review of the record before he reached his conclusions, the three cases GSK cites are inapposite. (Br. at 13-14.) In those cases, the experts reached conclusions without support in the record or before they reviewed the record. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997); *Mahmood v. Narciso*, 549 Fed. Appx. 99, 103 (3d Cir. 2013); *Claar v. Burlington N. R.R. Co*., 29 F.3d 499, 502 (9th Cir. 1994).

GSK also asserts that Dr. Perri [redacted] Once again, this misrepresents Dr. Perri's testimony. GSK quotes his statement [redacted]

Dr. Perri's opinions employ reliable methods and are factually supported by the record. GSK's criticisms are meritless. At best, they are arguments GSK can make to the jury.

IV. The Jury Should Hear Dr. Stephen Schondelmeyer's Analysis Of How Insurers Assess The Economic Value Of Prescription Drugs

Dr. Stephen Schondelmeyer is a Professor of Pharmaceutical Management and Economics at the University of Minnesota. He received his Ph.D. in Administrative and Social Sciences in Pharmacy in 1984. He is a leading teacher and researcher in the fields of pharmaceutical management and economics. He has served as an adviser to numerous federal and state agencies with respect to prescription drug policies. He has also advised the Pharmacy

and Therapeutics ("P&T") committees of healthcare providers and insurers with respect to drug formularies and coverage policies. (SMF ¶ 256.) Dr. Schondelmeyer has spent much of his career analyzing the value of prescription drugs in the U.S. marketplace.

Plaintiffs asked Dr. Schondelmeyer to assume [redacted]:

[redacted]

GSK argues that these and all other opinions expressed by Dr. Schondelmeyer should be excluded because [redacted] (Br. at 15.) All three objections rest on mischaracterizations of Dr. Schondelmeyer's testimony.

First, Dr. Schondelmeyer did not perform a "classic economic analysis" (Br. at 16) because that type of analysis was unnecessary to support his opinions. Dr. Schondelmeyer addressed whether [redacted] (SMF ¶¶ 259, 260.)

Courts routinely allow experts to rely on this kind of evidence to support opinions about market behavior and values. *See, e.g., CB Aviation, LLC v. Hawker Beechcraft Corp*., 2011WL

WL 5386359, at *5-6 (E.D. Pa. Nov. 8, 2011) (in assessing product's value, expert could rely on discussion with manufacturer, trade publications, and his own experience); *see also Terry v. McNeil-PPC, Inc.*, 2016 WL 807377, at *3-5 (E.D. Pa. Mar. 2, 2016) (marketing expert could rely on his experience and defendant's internal documents to assess effects of drug company's marketing efforts on consumers and healthcare providers); *Wonderland Nurserygoods Co. v. Thorley Indus., LLC*, 2013 WL 6328772, at *4 (W.D. Pa. Dec. 5, 2013) (expert could "rely on conversations with manufacturers and retailers" in assessing "market share or consumer behavior within a market"); *In re Sulfuric Acid Antitrust Litig*., 235 F.R.D. 646, 654 (N.D. Ill. 2006) (Rule 703 permits experts to rely "on all manner of underlying data . . . including interviews, reports prepared by third parties, clinical and other studies, and technical publications.").

Second, contrary to GSK's assertion, Dr. Schondelmeyer did not purport to opine about any [redacted] (Br. at 17.) His opinions address [redacted]. This objective inquiry is an appropriate subject for expert testimony, especially in a technical field of decision-making -- [redacted] -- in which jurors are unlikely to have any personal experience.[7]

[7] GSK asserts that Dr. Schondelmeyer previously testified about a party's subjective "intent/state of mind" in *Healthpoint, Ltd. v. Ethex Corp.*, 2001 WL 36101315 (W.D. Tex. Sept. 7, 2001) (Br. at 17). That case is irrelevant, however, because Dr. Schondelmeyer addresses a purely objective question here: whether a reasonable insurer would pay for GSK's drugs after full disclosure of the conditions at Cidra. In addition, GSK argues that his testimony is "strikingly similar" to that of an expert who improperly substituted his own opinions for the "direct testimony" of knowledgeable individuals in *Floorgraphics, Inc. v. News America Mktg. In-Store Servs.*, 546 F. Supp. 2d 155 (D.N.J. 2008) (Br. at 18). But in that case, the expert's opinions ***conflicted*** with the statements of knowledgeable individuals. *Id*. at 177. By contrast, Dr. Schondelmeyer's opinions are fully consistent with Plaintiffs' "direct testimony."

GSK takes fragments of Dr. Schondelmeyer's testimony out of context, but his reports and testimony as a whole show that he did not purport to opine [redacted]:

[redacted]

Third, it is simply untrue that Dr. Schondelmeyer formed his opinions [redacted]. (SMF ¶ 261.)[8]

[8] GSK notes that Dr. Schondelmeyer was [redacted] (Br. at 18-19.) As discussed above, however, Dr. Schondelmeyer [redacted] This distinguishes him from the experts in cases cited by GSK. *See Wolfson-Verrichia Grp., Inc. v. Metro Commercial Real Estate*, Inc., 2013 WL 1286184, at *12-13 (E.D. Pa. Mar. 28, 2013) (rejecting expert's real estate valuation because, among other things, it was directly contradicted by other evidence); *Bethea v. Bristol Lodge Corp*., 2003 WL 21146146, at *7-8 (E.D. Pa. May 19, 2003) (expert failed to cite any "industry standard" or "custom and usage in the industry"); *In re Fosamax Prods. Liab. Litig.,* 645 F.

GSK quotes [redacted] (SMF ¶ 210.) Dr. Schondelmeyer's opinions are supported by their testimony. Moreover, he specifically explained in [redacted]. (SMF ¶ 262.) If GSK wants to challenge Dr. Schondelmeyer's opinions [redacted], it can seek to do so before the jury.[9]

V. The Jury Should Hear Dr. Conti's Analysis Of Plaintiffs' Damages

Dr. Rena Conti is an Associate Professor at Boston University's Questrom School of Business, and previously taught at the University of Chicago's Harris School of Public Policy. She also serves as an economist for the FDA's Center for Drug Evaluation and Research. She received her Ph.D. in health policy, with a concentration in economics, from Harvard University.

Supp. 2d 164, 192 (S.D.N.Y. 2009) (expert's report was "replete" with "conjecture" of "the knowledge, motivations, intent, state of mind, or purposes of Merck, its employees, the FDA, or FDA officials"); *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (expert lacked "knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think").

[9] GSK asserts that Dr. Schondelmeyer was criticized for "ignoring contradictory record evidence" in *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc*., 2005 WL 1396940, at *18 (S.D. Ohio June 13, 2005). (Br. at 19.) In that case, however, Dr. Schondelmeyer's testimony was addressed on summary judgment, not under *Daubert*. And as already noted, his testimony in the present case is fully consistent with the testimony of Plaintiffs' other witnesses.

She focuses her research on the U.S. market for prescription drugs and the pricing of pharmaceutical products, topics on which she has testified before Congress. (SMF ¶ 263.) Like all of Plaintiffs' other experts, her qualifications and expertise are unchallenged by GSK.

Plaintiffs' counsel asked [redacted]. (SMF ¶¶ 264-66.)

GSK seeks to exclude Dr. Conti's testimony on four purported grounds: (1) "Dr. Conti impermissibly bases her opinion on a legal interpretation" of the FD&C Act; (2) she "offers no reliable economic methodology for her opinion"; (3) in the absence of a reliable methodology, she "regurgitates" Plaintiffs' allegations; and (4) she overlooks "economic realities" in calculating damages. (Br. at 20.) All four arguments for exclusion are baseless. Dr. Conti's opinions are well-supported in economic literature and fully meet *Daubert*'s standards.

A. Dr. Conti Properly Concluded That GSK's Drugs Lacked Economic Value

1. Dr. Conti did not express impermissible legal opinions

Dr. Conti's analysis [redacted]. (SMF ¶ 265.) Dr. Conti applied standard microeconomic principles to reach that conclusion. She did not express a legal opinion. Instead, she properly made a legal ***assumption***. She assumed that [redacted]

[redacted] (SMF ¶ 264.) Dr. Conti properly considered [redacted].

Thus, GSK has confused legal assumptions with legal conclusions. The courts are not confused. They allow experts to testify about business practices and behavior based on legal considerations, as long as the experts avoid expressing ultimate legal conclusions. *See, e.g., Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) (former SEC counsel's testimony could provide "important context" to aid the jury in determining whether investment firm's behavior indicated scienter with regard to statutory registration requirements); *United States v. Leo*, 941 F.2d 181, 196-97 (3d Cir. 1991) (expert could testify about defense industry behavior in relation to a military procurement statute); *United States v. Universal Rehab. Serv., Inc.*, 1996 WL 297575, at *10 (E.D. Pa. May 31, 1996) (expert could testify about "complex statutes or issues outside of the general knowledge of the jury" because the expert "did not opine on the ultimate legal issue of whether a fraud had been committed").[10]

GSK also criticizes Dr. Conti's analysis on the ground that [redacted] (Br. at 21 n.2.) That is a non sequitur. The purpose of Dr. Conti's analysis [redacted]

[10] Citing two cases, GSK argues that experts may not testify about "the legal effect of federal regulations" and "the meaning and application of terms in a statute or regulation." (Br. at 20-21.) Neither case undermines Dr. Conti's analysis. *See Jordan v. Temple Health Sys., Inc.*, 2018 WL 3649019, at *2-3 (E.D. Pa. Aug. 1, 2018) (expert's report consisted mostly of "recitations of case law and federal regulations," and his testimony would not assist the jury "beyond what will already be provided by fact witnesses and this Court's legal instructions"); *In re Wellbutrin SR Antitrust Litig.*, 2010 WL 8425189, at *6, 7 (E.D. Pa. Mar. 31, 2010) (barring expert testimony that expressed "conclusions" of patent law, but allowing testimony that explained "relevant background issue[s] concerning patent law").

[redacted] (SMF ¶¶ 264-66.)

Finally, Dr. Conti's conclusion is consistent with the record. Plaintiffs' corporate representatives testified that [redacted]. (SMF ¶ 210.) Dr. Conti's conclusion is also consistent with the testimony of [redacted] (SMF ¶ 211.) [redacted]

2. Dr. Conti's methodology is reliable

In conducting her analysis, Dr. Conti applied [redacted]

GSK argues that Dr. Conti's opinions [redacted]. (SMF ¶ 268.)

GSK argues further that her analysis is "superficial" and "conclusory." (Br. at 22.) This ignores the record. [redacted]

[redacted] (SMF ¶ 269.)

If GSK wishes to argue that Dr. Conti's analysis is superficial and conclusory, it can make that argument to the jury. *See, e.g.*, *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (the "burden of exploring the facts and assumptions underlying the testimony of an expert witness is on opposing counsel during cross-examination"); *Allstate Ins. Co. v. Guagliardo Plumbing, Heating, & Air Conditioning, Inc*., 2017 WL 1928384, at *3 (M.D. Pa. May 10, 2017) (supposed flaws in methodology "are proper for cross examination of the witness and perhaps argument to the jury," but do not warrant exclusion under *Daubert*).

3. Dr. Conti's analysis properly incorporates Plaintiffs' testimony

GSK attacks Dr. Conti's credibility by accusing her of [redacted] (Br. at 20, 23.) GSK's argument seeks to usurp the jury's role as the arbiter of a witness's credibility. Moreover, as discussed above, Dr. Conti's analysis [redacted]. Indeed, if Dr. Conti failed to cite any testimony, GSK would undoubtedly complain that her opinions were factually baseless.

GSK asserts that Dr. Conti's reply report [redacted]

[redacted]

[redacted] Her reply report is entirely consistent with that statement.

GSK also argues that Dr. Conti's analysis [redacted]

[redacted]

B. Dr. Conti Properly Excluded [redacted]

GSK argues that Dr. Conti's damages calculations are "fundamentally flawed" because they omit [redacted]. (Br. at 24.) Neither argument is a basis for excluding Dr. Conti's analysis under *Daubert*.

[redacted] (SMF ¶ 271.)

[redacted]

[redacted]

[redacted] According to GSK, "When evaluating damages claims for prescription drugs, courts have rejected claims for the full price of drugs without deducting the cost of the therapeutic alternatives." (Br. at 25.) GSK then cites two cases, neither of which supports its position: *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014), *aff'd*, 806 F.3d 71 (2d Cir. 2015); *In re Celexa & Lexapro Mktg. & Sales Practices Litig*., 325 F.R.D. 529 (D. Mass. 2017). (Br. at 25.)

Neither case involved cGMP violations. Both involved fraudulent "off-label" marketing that targeted doctors, not third-party payers. In both cases, the chain of causation ran through each doctor's decision to prescribe the defendant's drug versus another drug -- a comparative choice, based on each drug's relative merits, which the defendants' fraud improperly skewed. *See Sergeants Benevolent Ass'n*, 20 F. Supp. 3d at 327-28; *Celexa*, 325 F.R.D. at 539-40.

The present case is different. The relevant decision skewed by GSK's fraud was not a doctor's decision to prescribe a Cidra drug versus an alternative drug, but Plaintiffs' decision to maintain insurance coverage for Cidra's drugs at all. Instead of a comparative choice, this was a yes-or-no choice. Indeed, this Court's Rule 12(b)(6) decision recognized the yes-or-no character of the choice, viewed from the doctor's and patient's perspective. The Court pointed out that if Plaintiffs had withdrawn insurance coverage for the At-Issue Drugs, doctors likely would have rejected the At-Issue Drugs as a practical option for their patients -- regardless of any

comparison with other drugs. As the Court stated, "physicians would have not prescribed the at-issue drugs *at all*." (Dkt. No. 105, at 12, emphasis in original.)

Furthermore, GSK's theory fails to work even on its own terms as a comparison. GSK wants to compare materially non-compliant products made at Cidra with compliant products made by other drug companies. That is an apples-to-oranges comparison. Compliant products had economic value to insurers, while Cidra's products did not. GSK's theory is radically different from the off-label marketing cases cited by GSK, where the drugs on both sides of the theoretical comparison were cGMP-compliant.

GSK's theory not only involves a false comparison but also leads to unacceptable results. [redacted] (SMF ¶ 272.) Taken to its ultimate conclusion, GSK's argument is self-refuting.

Finally, [redacted] is consistent with the analysis applied by courts when they determine economic losses attributable to improperly manufactured products, including prescription drugs, under federal sentencing guidelines. In such cases, the courts conclude that the products are worthless, and therefore the extent of the loss is the full amount paid. They do not credit the wrongdoer with the cost of alternative products.[11]

[11] *See, e.g., United States v. Milstein*, 401 F.3d 53, 74 (2d Cir. 2005) ("contaminated medicine" may be found to be "worthless to the consumer"); *United States v. Gonzalez-Alvarez*, 277 F.3d 73, 78 (1st Cir. 2002) ("Because the milk would have been worthless had the scheme been terminated before the adulterated product was sold, it should not acquire an increased value merely because the defendant's scheme was successful and the tainted milk reached the

GSK's damages expert, Dr. Rao, [redacted] cannot justify invalidation of Dr. Conti's calculations under *Daubert*.[12]

CONCLUSION

GSK's *Daubert* motion should be denied.

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Respectfully submitted,

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consumers. . . . [T]here is no way to know with any certainty if anyone suffered ill-effects from consumption of the adulterated milk, but it would be irrelevant even if true. . . ."); *United States v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001) ("[M]edical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get what they bargained for. . . . [T]he defendant's gain is the appropriate measure of that loss."); *United States v. Marcus*, 82 F.3d 606, 610 & n.3 (4th Cir. 1996) (because "consumers would not purchase a drug of unknown safety and efficacy at any price," a drug company's gross sales "were the appropriate measure of the actual loss suffered by consumers"; irrespective of whether the drug "was actually safe and effective, customers suffered a loss by not receiving a drug of known safety and efficacy"); *United States v. Segredo*, 2010 WL 11519653, at *5 (S.D. Fla. Feb. 19, 2010) ("victimized buyers and end-users, who unknowingly acquired high growth hormones of unknown origin and without a verifiable chain-of-custody and pedigree" received "worthless" drugs and incurred "a loss as to the full value of the drugs"); *cf. United States ex rel. Compton v. Midwest Specialists, Inc*., 142 F.3d 296, 304 (6th Cir. 1998) (in a False Claims Act case, the government's loss consisted of the full contract price for the entire shipment of Army jeep components, even though only some failed quality tests; "*none* of them came with the quality assurance of a product that had been subjected to periodic production testing") (emphasis in original).

[12] Although Dr. Rao's analysis is riddled with errors on this and other points (see SMF ¶ 273), Plaintiffs have chosen not to burden the Court with a *Daubert* motion to exclude his testimony, or the testimony of any other GSK expert. Plaintiffs reserve the right, however, to move to exclude at trial the testimony of GSK's experts on grounds such as Fed. R. Evid. 403.

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CERTIFICATE OF SERVICE

Undersigned counsel certifies that on January 28, 2019 he served the foregoing Plaintiffs' Brief in Opposition to Defendant's *Daubert* Motion [Corrected] by email on the following counsel (the original Brief having been served on the same counsel by email on January 11, 2019):

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